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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,586	09/19/2005	Keiko Akimoto	V-314	8999
802	7590	09/29/2006	EXAMINER	
PATENTTM.US			SHEN, BIN	
P. O. BOX 82788			ART UNIT	
PORTLAND, OR 97282-0788			PAPER NUMBER	
			1655	

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/529,586

Applicant(s)

AKIMOTO ET AL.

Examiner

Bin Shen

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 3-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

The IDS received 6/6/2005 has been entered.

Election

Applicant's election with traverse of Group I, claim 1-2, in the reply filed on 9/1/2006 is acknowledged. The traversal is on the ground(s) that the searches and examination would be similar (no burden upon the examiner to examine the full scope of the claims). This is not found persuasive because the arguments ("search burden") are not applicable to lack of unity restriction rules (PCT Rule 13.1). Further, the inventions lack the same or corresponding special technical feature as noted in the last office action.

The requirement is still deemed proper and is therefore made FINAL.

Claims 3-9 are nonelected and thus are withdrawn from further consideration.

Claims 1-2 are presented for examination on the merits.

Specification

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and

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use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 refers to an additional diagnostic parameter which is not described in the specification. Thus, the specification does not provide support for the claim. One skilled in the art would conclude that the inventors were not in possession of the claimed invention since it is not clear what an additional diagnostic parameter is. Thus, the claims fail to comply with the written description requirement. Further, since this Examiner cannot determine what additional diagnostic parameter is claimed, it cannot be searched.

3. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not provide any guidance on what an additional diagnostic parameter is, and thus the artisan would have been unable to determine what an additional diagnostic parameter is and compare with the test result to make a diagnosis. It would have been an undue burden on one of skill in

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the art to make or use the claimed invention. The claims fail to meet the enablement requirement for the "how to make" prong of 35 U.S.C. 112, first paragraph. Thus, the skilled artisan would not been able to make and use the diagnosing method as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2 are vague and indefinite because the methods do not recite clear and positive steps. The body of claim 1 refers to "another low-concentration aqueous solution" (line 3) which is in reference to "low-concentration aqueous solution" in the preamble. It is not clear which solution is which? How many different "low-concentration aqueous solution" are tested in the method? What does "the other one" (line 5) refer to? Applicant is required to clearly set forth positive steps in this method. For example, applicant could recite step a, step b, etc. In claim 1, "characterized in that..." is confusing since it is not clear if the alkali and acid treatment happened before the laser correlation spectroscopy analysis or is the first step of this method.

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All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiselev et al. (English abstract only. Radiats Biol Radioecol 1999;39(1):64-78).

Kiselev teaches a method of diagnosing oncological diseases using laser correlation spectroscopy of blood plasma (abstract: "With the help of LCS blood plasma it is possible to show the difference in direction of homeostatic changes in animals with and without oncological disease...")

Kiselev does not teach the treatment of blood plasma with alkali and acid before LCS analysis.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kiselev by adding alkali and acid to samples because the adjustment of particular conventional working conditions (e.g., sample preparation) is deemed merely a matter of judicious selection and routine optimization which is well within the

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purview of the skilled artisan having the cited reference before him/her. One would have been motivated to make the modification because more homeostatic changes in the blood sample will be revealed under both the basic (alkali) and acidic conditions, and would reasonably have expected success in view of Kiselev's teaching that LCS of blood plasma can be used to diagnose oncological diseases.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

6. No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are

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unsuccessful, the examiner's supervisor, Dr. Terry McKelvey can be reached at (571) 272-0775.

A handwritten signature in dark ink, appearing to read 'M. Meller', followed by a horizontal line extending to the right.

**MICHAEL MELLER
PRIMARY EXAMINER**

B Shen

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